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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/546,201 04/10/00 POLO

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HM12/1206

EXAMINER

FOLEY, S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED:

12/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/546,201

Applicant(s)

POLO ET AL.

Examiner

Shanon A. Foley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-45 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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## **DETAILED ACTION**

### ***Election/Restriction***

The claims in this application involve a number of different products, which are claimed separately or in a variety of combinations. The claims involve the following subcombinations of expression cassettes, disclosed as usable together:

- A. Cassette(s) encoding double stranded RNA that induces interferon production
- B. Cassette encoding ribozyme or antisense RNA that promotes immune response
- C. Cassette encoding ribozyme or antisense RNA that promotes apoptosis
- D. Cassette encoding polypeptide that promotes apoptosis
- E. Cassette encoding polypeptide antigen from a pathogenic agent
- F. Cassette encoding cytokine polypeptide

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, drawn to interferon-inducing dsRNA subcombination A, classified in class 536, subclass 23.1.
- II. Claims 5-8, drawn to immune-response ribozyme or antisense subcombination B, classified in class 536, subclass 24.5.
- III. Claims 9-10, drawn to apoptosis ribozyme or antisense subcombination C, classified in class 536, subclass 24.5.

If group I, III, or III is elected, claims 11, 12, and 14-16 will be examined together with the elected group, to the extent that they read upon the elected group.

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- IV. Claim 13, drawn to combination of A + C (interferon-inducing dsRNA + apoptosis ribozyme or antisense), classified in class 536, subclass 24.5..
- V. Claim 17, drawn to combination of [A or B or C] + D (apoptosis polypeptide) , classified in class 536, subclass 23.5.
- VI. Claims 18-22, drawn to combination of [A or B or C] + E (pathogen antigen), classified in class 536, subclass 23.7.
- VII. Claims 23-25, drawn to combination of [A or B or C] + F (cytokine), classified in class 536, subclass 23.52.
- VIII. Claim 26, drawn to combination of A + E (interferon-inducing dsRNA + pathogen antigen) , classified in class 536, subclass 23.7.
- IX. Claim 27, drawn to combination of D +E (apoptosis polypeptide + pathogen antigen), classified in class 536, subclass 23.5.

If group VIII or IX is elected, claims 28-33 will be examined together with the elected group, to the extent that they read upon the elected group.

If group I, II, III, VIII or IX is elected, claims 34-44 will be examined together with the elected group, to the extent that they read upon the elected group.

- X. Claim 45, drawn to method of stimulating an immune response, classified in class 514, subclass 44.

If group X is elected, applicant is further required to elect a species of product used in the method, chosen from the products of group I, II, III, VIII or IX. If group VIII or IX is elected,

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the method claim 45 will be examined together with the product claim, to the extent that the method reads upon the elected product.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are drawn to distinct products, with distinct structures and functions. Each of the three products can be used independently of the others, for materially different purposes such as inducing interferon, promoting an immune response, and promoting apoptosis.

Inventions I and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, the interferon-inducing cassette can be used to induce an interferon response without the apoptosis-inducing ribozyme/antisense RNA, and the apoptosis-inducing ribozyme/antisense RNA can be used to induce apoptosis without the interferon-inducing RNA. See MPEP § 806.05(d).

Inventions IV and I are related as combination AC and subcombination A. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination A as claimed because it can rely upon the particulars of subcombination C for patentability. The subcombination A has separate utility such as inducing an interferon response without apoptosis.

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Inventions IV and III are related as combination AC and subcombination C. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because it can rely upon the particulars of subcombination A for patentability . . The subcombination C has separate utility such as inducing apoptosis without inducing an interferon response.

Inventions V and (I-III) are related as combination (A, B, or C) + D and subcombination A, B, or C. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because it can rely upon the particulars of the encoded apoptosis-inducing polypeptide. The subcombination has separate utility such as inducing interferon, promoting an immune response, or inducing apoptosis in the absence of an expressed protein.

Inventions VI and (I-III) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant

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case, the combination as claimed does not require the particulars of the subcombination as claimed because it can rely upon the particulars of the encoded antigen. The subcombination has separate utility such as inducing interferon, promoting a nonspecific immune response, or inducing apoptosis.

Inventions VII and (I-III) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because it can rely upon the particulars of the encoded cytokine. The subcombination has separate utility such as inducing interferon, promoting an immune response, or inducing apoptosis.

Inventions VIII and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because it can rely upon the particulars of the encoded antigen. The subcombination has separate utility such as inducing interferon.

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Invention IX is unrelated to inventions I-VIII, because it does not require any of the subcombinations of groups I-III, and uses a combination of materials different from the combinations required in groups IV-VIII.

Inventions (I-III) and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product, as claimed, can be used in a materially different process, such as inducing a nonspecific immune response in a host (inventions I, II) or inducing apoptosis (invention III).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and because the inventions require divergent searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).



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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 7:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley  
December 4, 2000

  
**MARY E. MOSHER**  
**PRIMARY EXAMINER**  
**GROUP 1800**  
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